Determination of Maximum Therapeutic Benefit (MTB)

Policy Statement

Maximum Therapeutic Benefit (MTB) is determined following a sufficient course of care, where demonstrable improvement would be expected in a patient’s health status and one or more of the following are present:

- The patient has returned to pre-clinical/pre-onset health status
- Meaningful improvement has occurred; however, there is no basis for further meaningful improvement
- Meaningful improvement has occurred and there is no basis for further supervised in-office treatment
- The patient no longer demonstrates meaningful clinical improvement, as measured by standardized outcome assessment tools.
- Meaningful improvement, as measured by standardized outcome assessment tools, has not been achieved
- There is insufficient information documented in the submitted patient health care record to reliably validate the response to treatment

It is the responsibility of the treating health care provider to maintain a patient health care record that includes periodic measures of treatment response by employing valid, reliable and relevant outcome assessment tools. Further, it is the responsibility of the treating health care provider to include sufficient data in clinical submissions, so that a peer reviewer can render a reasonable determination on baseline status and/or treatment response.

Once MTB has been determined, the treating health care provider is accountable to either:

1. amend the current plan of care based upon current best-evidence
2. refer the patient for an appropriate therapeutic regimen
3. discharge the patient from the current therapeutic regimen

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Purpose

This policy has been developed to describe the current evidence-basis for the determination of maximum therapeutic benefit (MTB) in the management of neuromusculoskeletal disorders. Additionally, this policy acknowledges individual health care provider accountabilities in assessing for MTB and appropriate clinical decision-making once MTB has been reached.

Summary

- Meaningful clinical change (MCIC/MCID) has been calculated for most common standardized outcome assessment tools
- The application of valid and reliable outcome assessment tools in the management of neuromusculoskeletal disorders is generally viewed as a core component of “best practice”
- In order to make a valid and reliable determination of meaningful progress toward goals (MCIC) and/or MTB, it is essential that the patient health care record include the appropriate application of relevant standardized outcome assessments (OA)
- Progress towards goals can be assessed at points in time following the index visit, where there is a substantiated basis for anticipating meaningful clinical change
- Recovery patterns for a variety of neuromusculoskeletal conditions generally show clinically meaningful change (e.g., >50% of the overall improvement for spine-related disorders) with care occurs within 4-6 weeks of the index visit
- The emerging evidence for nonspinal neuromusculoskeletal conditions parallels that of spine-related disorders
- Short term treatment response is predictive of long term outcomes
- Exacerbations of LBP have been shown to resolve within a few days to two-three weeks
- Further meaningful improvement can occur only when there is a potential for MCIC

Scope

This policy applies to all in and out of network programs involving all provider types, where utilization review determinations about maximum therapeutic benefit are rendered. This policy also serves as a resource for peer-to-peer interactions in describing the position of Optum* by OptumHealth Care Solutions, LLC on the determination of maximum therapeutic benefit.

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Utilization Management Policy

Definitions

**Maximum Therapeutic Benefit (MTB)** – The application of the current therapeutic regimen has achieved its full potential benefit for this episode of the condition for which it was applied.

**Minimal Clinically Important Change (MCIC)** – The smallest change in the OA [outcome assessment] score that the patient perceives as beneficial i.e., clinically meaningful improvement

**Episode of Pain** – A period of pain lasting >24hrs, preceded and followed by a period of at least one month without pain

**Episode of Care** – Consultation or treatment preceded and followed by at least 3 months without treatment for the same complaint

**Recurrent Pain** – Pain that is present on less than half the days in a 12 month period occurring in multiple episodes. An episode of recurrence is characterized by a return of atypical pain and/or other symptoms and/or pain-related difficulty performing tasks and actions equivalent to the appropriate MCIC value for a minimum duration of 24 hours e.g., change in numeric rating scale of ≥ 2 points for chronic LBP.

**Chronic** – Pain reported on more than half the days in a 12 month period

**Flare-ups/Exacerbations** – Phases of increased pain, which may or may not be related to specific incidents, superimposed on a recurrent or chronic course. A flare-up or exacerbation is characterized by a return of atypical pain and/or other symptoms and/or pain-related difficulty performing tasks and actions equivalent to the appropriate MCIC value.

**Persistent** – Pain occurring 30 or more days within the preceding 12 months.

**Non-Persistent** – Pain occurring less than 30 days within the preceding 12 months.

**Supportive Care** – Treatment for patients who demonstrated clinically meaningful improvement, and have reached MTB, and there remain significant residual deficits in the performance of daily activities e.g., usually >20% on a Neck/Back Index, and alternative treatments have been applied or given consideration, and self-care measures alone are likely not to sustain previously achieved therapeutic gains i.e., progressively deteriorate when treatment is withdrawn, and care is rendered PRN i.e., not prescheduled

Background

Overview:
The determination of maximum therapeutic benefit (MTB) is predicated upon several key elements:
1. Assessment of clinically meaningful change
2. The timely application and recording of appropriate, valid and reliable measures of treatment response
3. An adequate period of time and/or treatment trial to reasonably anticipate that meaningful clinical improvement should take place
4. The probability of further meaningful clinical improvement

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Assessing Clinical Change:

A critical consideration in the determination of MTB is the assessment of clinical importance or meaningfulness of change in scores that occurs during an episode of care. While it is necessary to establish the statistical significance of relevant outcome measures, a statistically significant improvement may reflect a benefit that is clinically meaningless.[1] For the commonly employed outcome domains (i.e., pain, physical functioning, generic health status, work status, satisfaction, and global ratings), clinical importance and meaningfulness can best be determined from the interpretation of patient-centered data.

The need to be able to measure and assess the clinical relevance of the measured change from the patient’s perspective is important.[2] “...it is now widely recognized that patients’ perspectives are essential in making medical decisions and judging the results of treatment.”[3]

Clinicians can integrate the perspective obtained from patient self-reports once the meaning and clinical relevance of change scores can be accurately interpreted. The change in scores is calculated by measuring arithmetic differences between serially collected data i.e., standardized outcome instruments.

Minimal clinically important change (MCIC), “…is the smallest change in the OA [outcome assessment] score that the patient perceives as beneficial.”[4] Another analogous term, Minimal Clinically Important Difference (MCID) has been defined as “the smallest change that is important to patients.”[5] The MCIC and MCID differ in context. MCIC is a measure of meaningful change at the individual patient level. MCID refers to meaningful change within a group i.e., between patients. [3,6]

The basis for quantification and standardization of MCIC is to minimize the variability in clinician judgment of patient ‘change’ following treatment.[7] The inaccurate assessment of ‘change’ has been shown to mitigate the quality of clinician decision-making.[8]

MCIC/MCID for the most common standardized outcome assessment tools have been calculated. {Table 1}[9-18] Factors that have been shown to influence MCIC include the duration and severity of complaints at the initial visit (index visit), and the timing of data collection. In general, acute (recent onset) presentations require a larger difference between baseline and subsequent assessments to be viewed as meaningful. For example, “If a numerical rating scale (NRS) is used it seems reasonable to suggest that the MCIC should at least be 3.5 and 2.5 for patients with acute and chronic low back pain, respectively.”[3] Similarly, patients who present with low levels of pain or disability at the index visit would need lesser changes at follow-up for MCIC to be achieved.[4, 6] Additionally, the time interval between outcome assessments may influence the magnitude of change. In general, longer time periods in comparison to lesser intervals (6 weeks vs. 2 weeks) between measurements would be expected to demonstrate greater change scores.[2]

The calculations for meaningful clinical change have typically been derived using both statistical and descriptive methods. Statistical methods include measures of effect size, standard error of measurement, reliable change index, raw and percentage change scores, and optimal cutoff point (sensitivity/specificity).[5,19] Statistical assessments are generally best associated with MCID. Descriptive or anchor-based approaches are typically used to evaluate a patient’s own impressions of change.[19] These ‘global impressions of change’ scales constitute an external criterion or gold standard of clinically important change.[20] Descriptive methods have yet to establish standards of validity; however, they are viewed as being intuitively reasonable and clinically relevant.[19] The determinations of MCIC values are calculated by using statistical methodologies in combination with descriptive criteria.[3]
Application of Outcome Assessment Tools:

The application of valid and reliable outcome assessment tools in the management of neuromusculoskeletal disorders is generally viewed as a core component of “best practice.” At least one state education department has alerted providers to the need for including outcome measures as part of record keeping and documentation. The value of using standardized outcome assessment tools has been recognized in a number of international and multidisciplinary guidelines for a variety of common neuromusculoskeletal conditions.

In their texts Liebenson and Yeomans provide detailed summaries of the purposes, value, selection, implementation and interpretation of standardized outcome assessment tools. For most neuromusculoskeletal conditions the domains of Pain, Physical Functioning, and Satisfaction are viewed as part of a core set of outcome measures. Commonly cited pain scales include the Numeric Rating Scale and the Visual Analogue Scale. Measurement of physical functioning usually takes place using condition-specific questionnaires e.g., Oswestry Disability Index or the Roland-Morris Low Back Pain and Disability Questionnaire. Patient perceptions of change scales or global ratings of change scales are used to measure the domain of patient satisfaction with the outcome of care.

Global rating scales are used as external criteria that aid in the interpretation of validated core outcome measurements. These scales make intuitive sense in that they ask individual patients to provide measurable data concerning their subjective judgments about the meaning of change. For the most part, global rating scales have not been tested for reliability and validity. Accordingly, they are typically used to inform the interpretation of standardized outcome measures i.e., pain and physical functioning. Global ratings that convey responses of “much improved” and “very much improved” are broadly interpreted as clinically meaningful. The optimal number of response categories has been investigated. Scales of 7 to 10 points appear to provide the best balance of reliability, discriminatory power, utility and patient preferences.

In order to make a valid and reliable determination of meaningful progress toward goals (MCIC) and/or MTB, it is essential that the patient health care record include the appropriate application of relevant standardized outcome assessments (OA). The appropriate application of OA typically includes obtaining baseline measures at the index visit. Periodic assessments using the same measurement tools should take place during the course of care. “OA tools can be used on a weekly or monthly basis to review patient progress towards meaningful goals” MCIC values have been calculated in empirical studies for commonly used standardized outcome instruments. There is a growing consensus for the broad adoption of the interpretation of MCIC for outcome measurements for spine-related disorders.

The minimal [clinically] important change values adopted by the VII International Forum on Primary Care Research on Low Back Pain (Amsterdam, June 2006) are: 15/100 for the Visual analogue Scale, 2/10 for the Numerical Rating Scale, 5/24 for the Roland-Morris Disability Questionnaire, 10/100 for the Oswestry Disability Index, and 20/100 for the Quebec Back Pain Disability Questionnaire. In broadly grouping back pain outcome measures for assessment at the individual patient level, the panel recommended a 30% change from baseline values (initial visit for an episode of care) when compared with follow-up measurements [e.g., a raw change in sequential measurements of the numerical rating scale for pain is 2 points (6/10 to 4/10); the relative percentage change is 33%].
Recovery Patterns:

An understanding of recovery patterns and treatment response assists in the timely identification of progress towards goals, assessment of treatment effect, and identification of end-points in care due to maximum therapeutic benefit.

Progress towards goals can be assessed at points in time following the index visit, where there is a substantiated basis for anticipating meaningful clinical change. These “recovery milestones” represent points in care for follow-up assessment. The RAND expert panel study published in 1991 determined that an evidence-based assessment was not feasible; however, on average the typical patient was expected to show improvement in 4-6 weeks.[33] Since the publication by this multidisciplinary panel, there have been a number of studies that provide the foundation for an evidence-basis in the identification of recovery patterns. The timing is based upon typical recovery patterns with care, natural history, normative data, and/or longitudinal clinical studies. [Table 2][34-61]

Typically, recovery patterns for neuromusculoskeletal conditions involving the low back, neck, and headache disorders show that ≥50% of the overall improvement with care occurs within 4-6 weeks of the index visit. {Table 2} and {Table 3} [62-71] When patients are categorized via predictive modeling, the percentage of those showing significant improvement within 6 weeks rises considerably. {Table 4}[34,35,46,50-55,72-76] These same studies have consistently shown that short term treatment response is predictive of long term outcomes. {Tables 2 & 3} McGorry showed that exacerbations of LBP resolved within a few days (52%); within a week (16%); within two-three weeks (26%); even severe flare-ups usually resolved within nine days.[77]

In addition to primary research on recovery patterns for spinal disorders, other organizations and/or professional groups have established parameters about the timing for assessments of measurable treatment response, and/or the timely identification of progress towards goals, and/or identification of end-points in care. These guidelines, which encompass a wide range of conservative interventions for acute and/or chronic neck and back pain (with and without radicular signs), recommend the assessment of treatment response within 1-6 weeks.[23,44,26-28, 78-85]

The emerging evidence for nonspinal neuromusculoskeletal conditions parallels that of spine-related disorders. {Table 5} [74-76,86-98] Recovery patterns have been reported for a variety of conditions involving the shoulder [91-94], knee [74-76,86-91], ankle [97], and post-stroke care [95,96]. MCIC was demonstrable within three to five weeks when rehabilitation services were administered for patients presenting with knee osteoarthritis. [74,87,91] Subjects reported immediate clinically meaningful improvement following either hip manipulation or taping for patellofemoral pain.[75,76] Patients whose treatment included various types of physical therapy or guided self-care for shoulder impingement were responsive within 4 to 6 weeks.[93,94] Rehabilitative care for significant portions of individuals with adhesive capsulitis of the shoulder reported MCIC within 3 weeks.[91,92] Most patients achieved MTB at 6-weeks follow-up.[92] A systematic review of the course of recovery for acute ankle sprains identified a rapid decrease in pain i.e., within 2 weeks was commonly reported.[97] A substantial portion of subjects, who received various types of post-stroke (CVA) rehabilitative services, demonstrated meaningful clinical improvement at 3 and 6 weeks.[95,96]

Post-surgical rehabilitation recovery patterns have been reported for total knee arthroplasty (TKA) [86] and internal fixation of distal radius fractures [98]. As found with non-postoperative care, recovery patterns following these operative procedures reported meaningful clinical improvement at 4 and 6 weeks respectively. Most patients who received post-TKA rehabilitation approximated MTB at 12 weeks.
In addition to primary research on recovery patterns, other organizations have established parameters about the timing for assessments of measurable treatment response, and/or the timely identification of progress towards goals, and/or identification of end-points in care for groupings of nonspinal conditions. The assessment of treatment responsiveness within 2 weeks of initiating conservative care for soft-tissue disorders of the shoulder (impingement syndrome, adhesive capsulitis, rotator cuff injuries, bursitis, and tendinopathies) is recommended.[99,100] The assessment of patient response from noninvasive care management for carpal tunnel syndrome and non-traumatic elbow conditions is recommended following 2 weeks of initiating treatment.[101,102] For post-operative therapy following surgical decompression for carpal tunnel syndrome, a 1-month duration for re-evaluation has been recommended.[101] The continuation of the same care management should be reconsidered for patients that have been diagnosed with Achilles tendonitis and do not demonstrate meaningful improvement within 30-days of commencing therapy.[103] Clinically important outcomes for post-stroke patients have been reportedly assessed between 2 and 6 weeks following the initiation of a course of acupuncture treatment.[104]

Assessing the Probability of Further Meaningful Improvement:

The probability of further meaningful improvement ties into the three preceding elements for assessing MTB. Further meaningful improvement can occur only when there is a potential for MCIC. Standardized outcome measures provide the template for identification of MCIC. The timing of assessment should be consistent with fact-based expectations.

Another component in the determination of MTB, as it relates to the potential for further meaningful improvement, is the consideration of end-points for in-office treatment. When recovery milestones are reached and progress towards goals is such that outcome measures approximate normative data for asymptomatic populations or are indicative of mild deficits, which can typically be managed through a general exercise program or other self-care, then a determination that MTB from in-office supervised care has been reached is appropriate.[4,5,105]

Two “Decision Guides” have been developed to inform utilization review (UR) determinations. The MTB – Decision Making Flow sequentially describes the serial judgments required to make consistent determinations about MTB. The Integration of the Global Rating Scale with Core Outcome Measurements provides guidance in the interpretation of standard outcome measures (pain and physical function) in the context of a global measurement of satisfaction with treatment outcome. Four possible scenarios are described. The complexity of UR decision making, clinical considerations, and the degree of confidence in rendering a determination based on the information at hand are incorporated into this guide. Both Decision Guides are appended to this document.

References

2. Beaton DE. Understanding the relevance of measured change through studies of responsiveness. Spine 2000; 25:3192-3199

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82. The Dutch Institute for Health Care Improvement (CBO) Guideline for the Diagnosis and Treatment of Specific Acute and Chronic Low back Complaints 2004.

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100. Work Loss Data Institute. Shoulder (acute & chronic). *Work Loss Data Institute* 2008; Corpus Christi, TX
101. Work Loss Data Institute. Carpal tunnel syndrome (acute & chronic). *Work Loss Data Institute* 2008; Corpus Christi, TX
102. Work Loss Data Institute. Elbow (acute & chronic). *Work Loss Data Institute* 2008; Corpus Christi, TX
103. Work Loss Data Institute. Ankle & foot (acute & chronic). *Work Loss Data Institute* 2008; Corpus Christi, TX

Additional Resources

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Tables

Table 1 – MCIC for commonly employed outcome measures

Table 2 – Recovery Patterns & Dose-Response Associated with Conservative Nonpharmaceutical Treatments for Low Back Pain

Table 3 – Recovery Patterns & Dose-Response Associated with Conservative Nonpharmaceutical Treatments for Neck Pain and/or Headaches

Table 4 – Treatment Response Based Upon Patient Classification Schemes

Table 5 – Recovery Patterns & Dose-Response Associated with SMT and/or Physical Therapy for Nonspinal Musculoskeletal Disorders
## Table 1: MCIC for commonly employed outcome measures

<table>
<thead>
<tr>
<th>Citation</th>
<th>Domain / Tool</th>
<th>Study Characteristics</th>
<th>MCIC</th>
<th>F/U Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farrar</td>
<td>Pain / NRS</td>
<td>- N = 2724 - Retrospective analysis of controlled trials for: diabetic neuropathy, postherpetic neuralgia, chronic LBP, fibromyalgia, osteoarthritis - PGIC used as an external criterion</td>
<td>- 30% change from baseline - If baseline score was at least 4/10 then a 2 point change - Baseline was less than 4/10 then 0.5</td>
<td>5-12 weeks</td>
</tr>
<tr>
<td>Turner</td>
<td>Pain / VAS</td>
<td>- N = 1124 - Work-related LBP - Telephonic survey</td>
<td>- Baseline was at least 5/10 then a 2 point change (based on change in perceived disability) - Baseline was less than 5/10 then a 1 point change was clinically relevant based upon perceived change in function</td>
<td>N/A</td>
</tr>
<tr>
<td>Hagg</td>
<td>Pain / VAS</td>
<td>- N = 289 - RCT - Chronic LBP with or without LE complaints - Patients treated surgically and non-surgically</td>
<td>- 18-19 point change in 100mm scale</td>
<td>2 years</td>
</tr>
<tr>
<td>Fritz</td>
<td>Function / ODI</td>
<td>- N = 67 - Work-related Acute LBP with and without LE pain - PGIC used as an external criterion - Physical Impairment Scale: supported the construct validity of the PGIC</td>
<td>- 6%</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Hagg</td>
<td>Function / ODI</td>
<td>- N = 289 - RCT - Chronic LBP with or without LE complaints - Patients treated surgically and non-surgically</td>
<td>- 10%</td>
<td>2 years</td>
</tr>
<tr>
<td>Meade</td>
<td>Function / ODI</td>
<td>- N = 50 - RCT</td>
<td>- 8%</td>
<td>Weekly (6 weeks)</td>
</tr>
<tr>
<td>Taylor</td>
<td>Function / ODI</td>
<td>- N = 318 - LBP with and without sciatica - Surgical and non-surgical cases - 75% chronic</td>
<td>- 16.3%</td>
<td>Pats receiving PT and/or injections = 2 months Surgical pats = 6 months All @ 12 and 24 months</td>
</tr>
<tr>
<td>Stratford</td>
<td>Function / NDI</td>
<td>- N = 49 - Convenience sample from multiple physical therapy outpatient clinics - Eligibility criteria not described</td>
<td>- 10%</td>
<td>1 to 3 weeks</td>
</tr>
<tr>
<td>MacDermid</td>
<td>Function / NDI</td>
<td>- Systematic Review - N = 37 primary studies, 3 reviews, and 1 in-press paper were analyzed - Rankings of quality and descriptive syntheses were performed</td>
<td>- 10% for uncomplicated neck pain - 20% for cervical radiculopathy</td>
<td>Varied</td>
</tr>
<tr>
<td>Binkley</td>
<td>Function / LEFS</td>
<td>- N = 107 - Convenience sample from twelve physical therapy outpatient clinics - All LE conditions included - PGIC used as an external criterion - Correlated with SF-36 physical function score</td>
<td>- 9 scale points</td>
<td>At 1-2 days following baseline Weekly (4 weeks)</td>
</tr>
<tr>
<td>Beaton</td>
<td>Function / DASH</td>
<td>- N = 200 - Diverse subject group having either wrist/hand or shoulder problems</td>
<td>- 15 scale points</td>
<td>3 months</td>
</tr>
</tbody>
</table>

**Legend:**
- NRS = Numerical Rating Scale
- VAS = Visual Analog Scale
- ODI = Oswestry Disability Index (Revised)
- NDI = Neck Disability Index
- LEFS = Lowe Extremity Functional Scale
- DASH = Disabilities of the Arm, Shoulder and Hand Questionnaire

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### Table 2: Recovery Patterns & Dose-Response Associated with Conservative Nonpharmaceutical Treatments for Low Back Pain

<table>
<thead>
<tr>
<th>Study</th>
<th>Methods</th>
<th>Intervention</th>
<th>TX Period</th>
<th>TX Frequency</th>
<th>Outcome Variables</th>
<th>Follow-up Period</th>
<th>Results</th>
</tr>
</thead>
</table>
| Axen (2005) | - Prospective, convenience sample                                       | Usual Tx methods by each DC. SMT, traction, massage, advice, exercise          | 2 weeks   | 2 times per week | Self-reported “definite improvement” at the fourth return visit | End of treatment period | - ~ Two thirds of subjects improved considerably before the 4th return visit. In most cases, these patients did not require more than 3 visits  
- The “most favorable prognostic group” - 91% were definitely improved by the 4th return visit (N=223)  
- The “least favorable group” – 36% reported definite improvement by the 4th return visit (N=36)  
- The “intermediate group” = all other patients. 76% reported definite improvement by the 4th return visit  
- Patients with, who sought care within the first week of onset, as opposed to the second week, had twice the recovery rate |
|             | - Multi-center, clinic-based                                            |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - 65 practitioners, max 20 patients each (N=708)                        |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - Patients with and without radiating LBP                              |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - CX = <2wks duration and up to 30 days total pain in past year         |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - Patients stratified via predictive modeling into 3 projected response groupings |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
| Axen (2002) | - Prospective, convenience sample                                       | Usual Tx methods by each DC. SMT, traction, massage, advice, exercise          | 2 weeks   | 2 times per week | Self-reported “definite improvement” at the fourth return visit | End of treatment period | - The “most favorable prognostic group” - 84% were definitely improved by the 4th return visit (N=115)  
- The “least favorable group” – 30% reported definite improvement by the 4th return visit (N=116)  
- The “intermediate group” = all other patients. 63% reported definite improvement by the 4th return visit (N=384) |
|             | - Multi-center, clinic-based                                            |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - Maximum of 20 patients per clinician (N=615)                          |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - Patients with and without radiating LBP                              |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - CX = >2wks duration and >30 days total pain in past year              |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
| Leboeuf-    | - Prospective, uncontrolled clinical trial                              | Typical office care                                                           |           |              | LBP free:  
- Max pain score of 1/10  
- Max Oswestry score of 15% | 4th visit  
- 3 months  
- 12 months | - Most improvement, both when recorded as mean status for the whole cohort and as numbers of LBP-free individuals occurred early in the course of care.  
- A suitable time for appraisal was that the fourth visit, which usually took place within 2 weeks  
- Outcome status at the 4th visit is a strong predictor of status at 3 and 12 months |
| Yde (2004)  | - multicentered, clinic-based involving 115 chiropractors              |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - 875 patients with pain between T12 and the gluteal folds (may also have LE pain) |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - >2 weeks duration                                                     |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - >30 days total pain in past year                                     |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
|             | - no TX by DC in >6 months                                             |                                                                               |           |              |                                                          |                  |                                                                                                                                                                                               |
| Kohlbeck (2005) | - Prospective Cohort  
- 2 private practices  
- 68 subjects with non-specific LBP (with and without LE radiation) between 18-60 yrs and LBP >3 mos  
- SMT; info/advice about posture and body mechanics; exercise as appropriate (flexibility, aerobic, strengthening)  
- Initial period: 4/6 wks + 4-12 wks  
- 2-3 times per wk for the initial 4-6 wks. Subsequent visit frequency varied based upon clinical evaluation and patient feedback  
- Change in Pain & Disability Scale:  
  - 0-100 pt scale where 0 = most pain and disability  
  - MCIC = 10 points  
- 6 weeks  
- 3 months  
- 6 months  
- 12 months  
- 6 weeks = >90% of total improved  
- 3 months = no further change (end of TX period)  
- 6 months = minimal (insignificant) additional improvement  
- 12 month s = status approx. the same as 6 weeks |
| --- |
- 4 hospital physical therapy clinics  
- 240 patients between 18-65 with LBP (regional or with LE radiation) of 4-12 wks duration  
- Maintenance of usual activities; routine physician mgt. + analgesics; and either:  
  - Educational pamphlet  
  - Manual therapy (mobilization or SMT as described by Maitland or Cyriax)  
  - Interferential current (IFT)  
  - Combined MT & IFT  
- 8 weeks  
- 4-10 visits  
- RMDQ: 3 or more point change = MCIC  
- McGill Pain Questionnaire  
- EuroQol (EQ5D): quality of life measure  
- SF36  
- 8 weeks  
- 6 months  
- 12 months  
- All clinically significant improvement occurred within the 10 week treatment period as calculated by the RMDQ, McGill and EQ5D.  
- The “Role Physical” and “Bodily Pain” scales (SF-36) showed MCIC at the end of the treatment period. Additional significant improvement occurred amongst all groups at 6 and 12 months follow-up. |
| Cherkin (1998) | - RCT  
- Large staff model HMO  
- 4 private chiropractic practices  
- 321 adults ages 20 to 64 with LBP persisting 7 days or more after PCP index visit.  
- 59% of patients had pain < 3 wks duration; most all had pain < 6 wks duration  
- Analgesics PRN DC:  
  - HVLA SMT  
  - Ice  
  - Brief localized massage  
  - Exercise and/or activity recommendations at provider’s discretion  
  - McKenzie  
  - L/S support cushion  
  - McKenzie booklet, “Treat Your Own Back”  
  - No other therapy  
- 1 month  
- 1-8 visits  
- DC: Mean = 6.9  
- PT: Mean = 4.6  
- RMDQ:  
  - MCIC = 2.5  
  - MCMC = 1.5  
- 4 weeks  
- 12 weeks  
- 24 months  
- Both outcome scales indicated that all clinically significant change occurred within 4 weeks.  
- These results were maintained for all follow-up intervals for DC, PT and booklet groups. |
| Stig (2001) | - Uncontrolled clinical trial  
- 158 subjects with non-specific LBP (with and without LE radiation)  
- > 2 wks duration  
- Total of > 4 wks of LBP in last 12 mos.  
- 19 private chiropractic practices  
- Usual Tx methods by each DC.  
  - SMT, traction, massage, advice, exercise  
- 12 weeks  
- 12 visits: (gradual reduction in frequency over time)  
- NRS: improvement = 2/10  
- Global Improvement Scale  
- Each visit  
- 50% of patients “improved” at 4 visits (2 weeks)  
- 62% at 6 visits (3 weeks)  
- 70% at 8 visits (4-5 weeks)  
- 75% of patients “improved” at 12 weeks (some of these patients reported improvement before 12 weeks) |

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# Utilization Management Policy

<table>
<thead>
<tr>
<th>Hurwitz (2002) [41]</th>
<th>Basis in the literature</th>
<th>Comparison of Clinical Outcomes</th>
<th>Baseline to 6 Wks:</th>
<th>Baseline to 6 mos:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- RCT</td>
<td>- Capitated health care network</td>
<td>- 681 patients at least 18 yrs old having LBP (58% with LE radiation)</td>
<td>- 40% with &gt; 1 yr duration</td>
<td>- Discretionary Baseline to 6 Wks:</td>
</tr>
<tr>
<td>- Medical Care Only (MD):</td>
<td>- advice/instructions on proper back care/exercises</td>
<td>- analgesics, muscle relaxants, anti-inflammatory medication</td>
<td>- advice on weight-loss, bed rest and/or physical activity</td>
<td>DC:</td>
</tr>
<tr>
<td></td>
<td>- SMT</td>
<td>- mobilization</td>
<td>- advice/instructions on proper back care/exercises</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 1 or more (at the discretion of the PT): heat/cold, ULS, EMS, traction, soft-tissue/joint mobs, supervised exercise and home exercise</td>
<td></td>
<td></td>
<td>- 0-8 (range)</td>
</tr>
<tr>
<td>- Chiropractic Care Only (DC):</td>
<td>- SMT</td>
<td>- mobilization</td>
<td>- advice/instructions on proper back care/exercises</td>
<td>DC:</td>
</tr>
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<td></td>
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</tr>
<tr>
<td>- Medical Care with Physical Therapy (MDpt):</td>
<td></td>
<td></td>
<td></td>
<td>- 3.7 (mean)</td>
</tr>
<tr>
<td></td>
<td>- MD as previously described +</td>
<td>- instruction on proper back care from the PT</td>
<td></td>
<td>- 3 (median)</td>
</tr>
<tr>
<td></td>
<td>- 1 or more (at the discretion of the PT): heat/cold, ULS, EMS, traction, soft-tissue/joint mobs, supervised exercise and home exercise</td>
<td></td>
<td></td>
<td>Baseline to 6 months:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DC:</td>
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<td></td>
</tr>
<tr>
<td>- Chiropractic Care with Physical Modalities (DCpm):</td>
<td></td>
<td></td>
<td></td>
<td>MD:</td>
</tr>
<tr>
<td></td>
<td>- DC care as previously described +</td>
<td></td>
<td></td>
<td>- 2.9 (mean)</td>
</tr>
<tr>
<td></td>
<td>- 1 or more of the following (at the discretion of the DC): heat/cold, ULS, EMS</td>
<td></td>
<td></td>
<td>- 2 (median)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- 1-23 (range)</td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRS:</td>
<td>- Most severe pain</td>
<td>- Average pain</td>
<td>- RMDQ:</td>
<td>- MCIC @ 6 wks = 2 points</td>
</tr>
<tr>
<td></td>
<td>- Baseline to 6 wks</td>
<td>- Baseline to 6 mos</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMC for disability (RMDQ) occurred for all groups @ 2 wks, 6 wks and 6 mos.</td>
<td></td>
<td></td>
<td>Mean reductions in disability were greatest during the first 2 wks except for the MDpt group, which showed the greatest reduction between 6 wks and 6 mos.</td>
<td></td>
</tr>
</tbody>
</table>

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#### Utilization Management Policy

<table>
<thead>
<tr>
<th>Hurwitz (2002) [42]</th>
<th>681 patients at least 18 yrs old having LBP (58% with LE radiation); 40% with &gt; 1 yr duration</th>
</tr>
</thead>
</table>

**Chiropractic Care Without Physical Modalities (DC):**
- SMT
- mobilization
- advice/instructions on proper back care/exercises

**Chiropractic Care with Physical Modalities (DCpm):**
- DC care as previously described +
  - 1 or more of the following (at the discretion of the DC):
    - heat/cold, ULS, EMS

<table>
<thead>
<tr>
<th>At provider discretion</th>
<th>Up to 6 months</th>
</tr>
</thead>
</table>

**Discretionary Baseline to 6 Wks:**
- DC:
  - 2.96 (mean)
  - 3 (median)
- DCpm:
  - 3.34 (mean)
  - 3 (median)

**6 Wks to 6 mos:**
- DC:
  - 1.78 (mean)
  - 1 (median)
- DCpm:
  - 1.84 (mean)
  - 1 (median)

**Baseline to 6 mos:**
- DC:
  - 4.74 (mean)
  - 4 (median)
- DCpm:
  - 5.18 (mean)
  - 5 (median)

**NRS:**
- Most severe pain
  - Average pain
  - MCIC = 2.0

**RMDQ:**
- MCIC = 3 pts

**Secondary Measures:**
- Cut-down days
- Bed days
- OTC meds days
- Rx meds days

<table>
<thead>
<tr>
<th>2 weeks</th>
<th>4 weeks (phone interview)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 weeks</td>
<td>6 months</td>
</tr>
</tbody>
</table>

**Baseline to 2 wks**
- The greatest mean decrease in most severe pain intensity occurred in the first 2 wks:
  - 38% of subjects = > 2 pts reduction @ 2 weeks
  - 52% of subjects = > 2 pts reduction @ 6 weeks
  - 60% of subjects = > 2 pts reduction @ 6 months
- At 2 and 6 wks fu, a greater proportion of the DCpm group achieved 2+ points decrease in most severe pain; however, the same average pain intensity reduction (50%) was reported in both groups.
- At 6 mos there were no differences in pain measures between groups.
- Disability decreased by 3 or more points in:
  - 37% of subjects @ 2 wks
  - 48% @ 6 weeks
  - 55% @ 6 months
- Proportions of subjects showing improved disability were somewhat greater in the DCpm group at 2 and 6 weeks but not at 6 months.
- Cut-down days:

<table>
<thead>
<tr>
<th>DC</th>
<th>DCpm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline to 2 wks</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>2.6</td>
</tr>
<tr>
<td>%&gt;0 days</td>
<td>47.3</td>
</tr>
<tr>
<td>2 wks to 6 wks</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3.0</td>
</tr>
<tr>
<td>%&gt;0 days</td>
<td>43.8</td>
</tr>
<tr>
<td>Baseline to 2 wks</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>0.3</td>
</tr>
<tr>
<td>%&gt;0 days</td>
<td>10.1</td>
</tr>
<tr>
<td>2 wks to 6 wks</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>0.3</td>
</tr>
<tr>
<td>%&gt;0 days</td>
<td>7.1</td>
</tr>
<tr>
<td>OTC Meds days</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3.6</td>
</tr>
<tr>
<td>Median</td>
<td>2</td>
</tr>
<tr>
<td>2 wks to 6 wks</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>57.4</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Study / Year</th>
<th>Study Design</th>
<th>Key Details</th>
<th>Data Recorded</th>
<th>Visit Frequency</th>
<th>NRS</th>
<th>RMDQ</th>
<th>Follow-Up Duration</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hurwitz (2006)</td>
<td>- RCT</td>
<td>Long-term follow-up on earlier study population</td>
<td>610 of original 681 (89.6%) subjects</td>
<td>Up to 18 months</td>
<td>Visit frequency after 6 months not reported other than a statement that the number of visits was equivalent for all treatment groups.</td>
<td>- Most severe pain - Average pain - MCIC = 2.0</td>
<td>18 months</td>
<td>At 18 months there were: - No clinically important change in average or worst pain as reported at 6 wks, 6 months and 12 months - No clinically important change mean level of low back disability compared with 6 wks, 6 months and 12 months</td>
</tr>
<tr>
<td>Chang (2002)</td>
<td>- RCT</td>
<td>200 adult subjects Ages 18 or older Non-specific LBP (with or without LE pain)</td>
<td>3 weeks to 6 months duration</td>
<td>3x/week (9 visits)</td>
<td>- Pain: VAS - Disability: RMDQ - MCIC: not defined</td>
<td>- 3 weeks - 6 months</td>
<td>- All groups showed improvement at 3 weeks - No further significant improvement at 6 months - No statistically significant between-group differences were found at either 3-week or 6-months</td>
<td></td>
</tr>
<tr>
<td>Leboeuf-Yde (2005)</td>
<td>- Prospective Descriptive Study</td>
<td>1054 subjects with non-specific LBP (with and without LE radiation) Mix of non-persistent and persistent duration - Multicenter, practice-based</td>
<td>Typical office care</td>
<td>Up to 12 months</td>
<td>Patient self-report of: - No LBP in last week - “Definitely better” on Global Improvement Scale</td>
<td>- 18 months</td>
<td>- Patient treatment response at the fourth return visit was predictive of status at 3 and 12 months i.e., patients not reporting improvement at 4th visit also likely to report no improvement with chiropractic care at 3 and 12 months</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Characteristics</th>
<th>Intervention Details</th>
<th>Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axen (2005)</td>
<td>- Predictive validity study; convenience sample&lt;br&gt;- 1057 patients with non-specific LBP (with and without LE radiation)&lt;br&gt;- Mix of non-persistent and persistent duration&lt;br&gt;- Multicenter, practice-based: 58 chiropractors</td>
<td>Typical office care: SMT with or without adjunctive modalities/procedures</td>
<td>Self-report of definite improvement&lt;br&gt;Fourth return visit&lt;br&gt;79% of “best” prognostic group were “improved” by the 4th return visit</td>
<td>At 4 weeks: &lt;br&gt;- There was a significant linear effect in pain intensity and disability favoring the larger number of visits (3 &amp; 4)&lt;br&gt;- There was no significant difference between 3 &amp; 4 visit frequencies&lt;br&gt;- There was no additional benefit from the inclusion of PM&lt;br&gt;At 12 weeks: &lt;br&gt;- No differences in pain or disability between groups&lt;br&gt;- No additional benefit from the inclusion of PM</td>
</tr>
<tr>
<td>Haas (2004)</td>
<td>- 72 adult subjects with regional LBP&lt;br&gt;- Age 18 and older&lt;br&gt;- Outpatient clinic located at Chiropractic College (WSCC)</td>
<td>- HVLA alone or&lt;br&gt;- HVLA + PM (1-2/visit)&lt;br&gt;- No exercise or self-care advice given</td>
<td>3 weeks&lt;br&gt;- 1x per wk&lt;br&gt;- 2x per wk&lt;br&gt;- 3x per wk&lt;br&gt;- 4x per wk</td>
<td>- 4 weeks&lt;br&gt;- 12 weeks&lt;br&gt;- No additional benefit from the inclusion of PM</td>
</tr>
<tr>
<td>Hoiriis (2004)</td>
<td>- 192 adult subjects&lt;br&gt;- Ages 21-59&lt;br&gt;- Uncomplicated LBP&lt;br&gt;- 2-6 weeks duration&lt;br&gt;- Baseline measures of pain and disability were modest. The opportunity for MCIC was limited by the “floor effect”&lt;br&gt;- Setting not described</td>
<td>- HVLA using drop techniques&lt;br&gt;- Acetaminophen - PRN</td>
<td>2 weeks&lt;br&gt;7 visits</td>
<td>- 2 weeks&lt;br&gt;- 4 weeks&lt;br&gt;- No additional benefit from the inclusion of PM</td>
</tr>
<tr>
<td>Andersson (1999)</td>
<td>- RCT&lt;br&gt;- 178 adult subjects&lt;br&gt;- Ages 20-59&lt;br&gt;- Non-specific LBP (with or without LE pain)&lt;br&gt;- 3 weeks to 6 months duration&lt;br&gt;- HMO: 2 locations</td>
<td>- Standard care: analgesics, anti-inflammatories, active (exercise) and passive physical therapy (ULS, TENS, diathermy, hot/cold packs, and/or corset)&lt;br&gt;- OMT: thrust, muscle energy, counterstrain, myofascial release</td>
<td>12 weeks&lt;br&gt;- 4 weekly visits&lt;br&gt;- 4 visits at 2 week intervals</td>
<td>- Each visit&lt;br&gt;- 12 weeks&lt;br&gt;- Both interventions resulted in similar outcomes at all assessment points for measures of pain intensity and functional disability.&lt;br&gt;- ~ 50% of improvement in pain intensity occurred by 6 weeks&lt;br&gt;- &gt; 50% improvement in disability achieved by 4 weeks</td>
</tr>
</tbody>
</table>

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### Utilization Management Policy

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Participants</th>
<th>Interventions</th>
<th>Duration</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brennan (2006) [50]</td>
<td>RCT</td>
<td>Multicenter; clinic-based (physical therapy)</td>
<td>123 adult subjects</td>
<td>Manipulation Group: - HVLA - Mobilization - AROM exercise Specific Exercise Group: - ROM exercises - Directional exercises (McKenzie) Stabilization Group: - Trunk strengthening and stabilization exercises</td>
<td>4 weeks</td>
<td>Up to 8 visits (2x/wk)</td>
<td>- ODI - Success = at least 50% decrease in disability score - Median visits for matched patients = 6.5 - Median visits for unmatched patients = 7 - 4 weeks - 1 year</td>
</tr>
<tr>
<td>Flynn (2002) [51]</td>
<td>Prospective cohort</td>
<td>2 military outpatient facilities</td>
<td>71 adult subjects</td>
<td>- Long lever lumbo-pelvic manipulation - Home exercise (pelvic-tilt) - Activity maintenance</td>
<td>2-12 days</td>
<td>1-3 visits</td>
<td>- ODI - Success = at least 50% decrease in disability score - 4 weeks</td>
</tr>
<tr>
<td>Childs (2004) [52]</td>
<td>RCT</td>
<td>Multicenter; physical therapy clinics</td>
<td>131 adult subjects</td>
<td>Manipulation Group: - Long lever lumbo-pelvic manipulation (2 sessions) - ROM exercise - Activity maintenance Exercise Group: - Low-stress aerobic - Strengthening exercise</td>
<td>4 weeks</td>
<td>5 visits</td>
<td>- ODI - Success = at least 50% decrease in disability score - 6 months</td>
</tr>
<tr>
<td>Cai (2009) [53]</td>
<td>Cohort</td>
<td>- 129 subjects - Pain and/or numbness in low back, buttocks and/or lower extremity - Out-patient orthopedic clinic</td>
<td></td>
<td>- Motorized mechanical traction</td>
<td>9 days</td>
<td>3 sessions</td>
<td>- ODI - Success = at least 50% decrease in disability score - NRS</td>
</tr>
<tr>
<td>Hicks (2005) [54]</td>
<td>Prospective cohort</td>
<td>Multicenter; physical therapy clinics</td>
<td>54 adult subjects over age 18</td>
<td>- Stabilization exercise program</td>
<td>8 weeks</td>
<td>16 visits (2x/wk)</td>
<td>- ODI - Success = at least 50% decrease in disability score - Somewhat improved = 12-49% decrease in ODI score</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Population</th>
<th>Interventions</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fritz (2005) [55]</td>
<td>Prospective Cohort + RCT</td>
<td>141 adult subjects (70 from a RCT [19] + 71 from another study [18])</td>
<td>Patients classified as favorably disposed to SMT based upon 2 pragmatic variables</td>
<td>Pre-treatment probability (45%) of a successful outcome increased to 85.5% for subjects positive on the pragmatic rule</td>
</tr>
<tr>
<td>Hsieh (2002) [56]</td>
<td>RCT</td>
<td>200 adult subjects</td>
<td>Cold</td>
<td>All groups showed significant improvement at 3 weeks. Combined therapy was statistically superior to MFT alone at 3 weeks. No other between group differences were found at 3 weeks or 6 months follow-up. Treatment effects noted at 3 weeks were maintained across groups at 6 months. SMT alone and MFT alone were as effective as combined SMT/MFT in the TX of Subacute LBP</td>
</tr>
<tr>
<td>Coste (1994) [57]</td>
<td>Cohort</td>
<td>103 subjects</td>
<td>Oral analgesics</td>
<td>Majority of subjects achieved MCIC for both pain and function within 2 days following the index visit. 90% of subjects were recovered within 2 weeks (recovery = resolution of pain and disability, and return to work)</td>
</tr>
<tr>
<td>Curtis (2000) [58]</td>
<td>RCT</td>
<td>295 adults subjects</td>
<td>Enhanced Care Group: Evidence-Based Mgt.</td>
<td>More patients (14%) receiving Manual Therapy had completely recovered after the first visit. Subjects who received 4 Manual Therapy treatments had a more rapid return to functional recovery (7.8 days) compared to less intense therapy (11.1 days). No differences over time in RMDQ scores were found</td>
</tr>
</tbody>
</table>

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**van der Roer (2008)**

- **RCT**
- 114 subjects
- Ages 18-65 years
- Non-specific LBP >12 weeks duration and inability to resume daily activities in the preceding 3 weeks
- 9 local research centers

<table>
<thead>
<tr>
<th>Intensive Group Training:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Exercise</td>
</tr>
<tr>
<td>- Back school</td>
</tr>
<tr>
<td>- Operant conditioning</td>
</tr>
<tr>
<td>Guideline Group:</td>
</tr>
<tr>
<td>- Usual physiotherapy</td>
</tr>
</tbody>
</table>

**Not described**

- **VAS**
- **RMDQ**
- **GPE**

**After index visit:**
- 6 weeks
- 13 weeks
- 26 weeks
- 52 weeks

- Analysis did not show any significant differences between groups on any outcome measure during the complete follow-up period, with one exception. After 26 weeks the Intensive Group Training protocol group showed greater pain reduction. This difference was absent at 52 weeks.

**Newell (2007)**

- **Cohort**
- 788 subjects
- LBP
- Private chiropractic practice

<table>
<thead>
<tr>
<th>Usual chiropractic care</th>
</tr>
</thead>
</table>

**Not described**

- **BQ**
- **PGIC**

**After index visit:**
- 4 weeks
- 12 weeks

- ~74% of patients were better at 4 weeks
- Further improvement was minimal up to 12 weeks
- The risk of being categorized as ‘not improved’ was reduced by 50% when the index visit occurred < 4 weeks following the onset of LBP.

**Grotle (2005)**

- **Cohort**
- 123 subjects
- Ages 18-60 years
- Acute LBP with and without neurological signs
- Primary care setting

<table>
<thead>
<tr>
<th>Usual primary care</th>
</tr>
</thead>
</table>

**Not described**

- **NRS**
- **RMDQ**

**Pain:**
- Weekly for 4 weeks
- 3 months

**Physical Functioning:**
- 4 weeks
- 3 months

- Subjects with and without neurological signs showed clinically meaningful improvement for pain as first weekly assessment. Those with 2 or more neurological signs exhibited a treatment response of lesser magnitude.
- At 4 weeks and 3 months 76% of the patients had recovered.

### Legend:

- **MCIC** – Minimal Clinically Important Change
- **RMDQ** – Roland Morris Disability Questionnaire
- **HVLA** – High Velocity Low Amplitude
- **Mobs** – Mobilization
- **NRS** – Numeric Rating Scale
- **PM** – Physical Modalities (hot packs, ultrasound, soft-tissue therapy, electrotherapy)
- **VAS** – Visual Analog Scale
- **MVK** – Modified Von Korff
- **ODI** – Oswestry Disability Index
- **ADL** – Activities of Daily Living
- **LEFS** – Lower Extremity Functional Scale
- **6MWT** – Six Minute Walk Test
- **TKA** – Total Knee Arthroplasty
- **GPE** – Global Perceived Effect
- **BQ** – Bournemouth Questionnaire
- **PGIC** – Perceived Global Impression of Change
- **GROC** – Global Rating of Change
- **WOMAC** – Western Ontario and McMaster Universities Osteoarthritis Index
- **PSFS** – Patient Specific Functional Scale

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### Table 3: Recovery Patterns & Dose-Response Associated with Conservative Nonpharmaceutical Treatments for Neck Pain and/or Headaches

<table>
<thead>
<tr>
<th>Study</th>
<th>Methods</th>
<th>Intervention</th>
<th>TX Period</th>
<th>TX Frequency</th>
<th>Outcome Variables</th>
<th>Follow-up Period</th>
<th>Results</th>
</tr>
</thead>
</table>
- 28 adult subjects  
- Ages 21 to 65  
- With neck pain, stiffness or tenderness of less than 12 wks duration; with and without neurological signs  
- Outpatient, primary contact clinic affiliated with a chiropractic research institution  
- Medical care took place at a primary contact center  | Chiropractic Care:  
- SMT + light massage  
- Activity modification as needed  
Medical Care:  
- Acetaminophen, NSAIDS, Mild narcotics  
- Activity modification as needed  
Self-Care:  
- Two 45 minute sessions including ergonomic advice  
- Educational booklet  | Up to 12 weeks  | - Pragmatic  
- At providers’ discretion  | - NRS  
- NDI  
- Perceived effect  | - 3 weeks after index visit  
- 12 weeks after index visit  | Chiropractic Care:  
- Median # visits = 8  
- Average = 8.6  
- 66% reported at least 50% improvement at 3 weeks  
- 92.6% reported at least 50% improvement at 12 weeks  
Medical Care:  
- Median = 5  
- Average = 5  |
| Evans (2002) [63] | - RCT  
- This study represents an extended follow-up on the same patient population recorded in reference # 54.  | | | | | | - The advantage of SMT/exercise and MedX over SMT alone was maintained at the two-year post-treatment follow-up. |
| Haas (2004) [64] | - RCT (Pilot Study)  
- 24 adult subjects  
- Ages 18 and older who met the IHS diagnostic criteria for uncomplicated, chronic cervicogenic headache  
- Faculty practice at a Chiropractic College (WSCC)  | HVLA  
- Discretionary applications of up to 2 modalities (heat, soft tissue massage and trigger point therapy) per visit  | 3 weeks  | - 1x per wk  
- 3x per wk  
- 4x per wk  | - Pain: MVK Pain Scale (three NRS)  
- Disability: MVK Disability Scale (three NRS)  
- MCIC was established a priori @ 20-25% of the baseline score  
- 10 point difference between groups  | - 4 weeks  
- 12 weeks  | At 4 weeks:  
- There was a significant linear effect in pain intensity and disability favoring the larger number of visits (3 &4)  
- There was no significant difference between 3 & 4 visit frequencies  
- Any additional benefit from the inclusion of PM was not determinable (all subjects received PM at least once and 66% received PM every visit)  
At 12 weeks:  
- Comparable differences in pain and disability between groups was maintained |

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<table>
<thead>
<tr>
<th>Authors</th>
<th>Study Type</th>
<th>Number of Subjects</th>
<th>Ages</th>
<th>Pain Type</th>
<th>Setting</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Follow-Up</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hurwitz (2002) [65]</td>
<td>RCT</td>
<td>336 adult subjects</td>
<td>Ages 18 to 70</td>
<td>Regional neck pain</td>
<td>HMO: 4 ambulatory sites</td>
<td>All subjects: Information about posture and body mechanics - Stretching, flexibility, and/or strengthening exercises - Ergonomic advice and workplace modifications</td>
<td>Manipulation: HVLA - With and without heat or EMS, or with heat and EMS combined Mobilization: Low velocity variable amplitude movements - With and without heat or EMS, or with heat and EMS combined</td>
<td>Not defined</td>
<td>NRS (MCIC = 2 points) - Average and most severe pain NDI (MCIC = 10%)</td>
</tr>
<tr>
<td>Bronfort (2001) [66]</td>
<td>RCT</td>
<td>191 adult subjects</td>
<td>Ages 20 to 65</td>
<td>Mechanical neck pain that had persisted for at least 12 months</td>
<td>Setting not stated</td>
<td>All Groups: Home exercise program SMT &amp; Low-Tech Exercise: HVLA (C/S; T/S) - Light soft-tissue massage - Aerobic warm-up; progressive strengthening exercises MedX Exercise: - Stretching, aerobic and strengthening exercise - MedX isometric exercises SMT Only: HVLA - Detuned ULS</td>
<td>11 weeks 20 one hour visits</td>
<td>NRS - NDI - 5-point OTC-Use Scale - 7-point satisfaction scale</td>
<td>During Treatment: - 5 weeks - 11 weeks Post-treatment: - 3 months - 6 months - 12 months</td>
</tr>
<tr>
<td>Thiel (2008) [67]</td>
<td>Prospective Cohort</td>
<td>19,722 subjects</td>
<td>Ages 16 to 100</td>
<td>Mixed population of neck/related symptoms</td>
<td>377 chiropractors</td>
<td>Manipulation: HVLA - Mechanical device - Toggle</td>
<td>Up to 7 days Single visit</td>
<td>- Global perceived change</td>
<td>Within 1 week of index visit</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Follow-Up</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bove (1998)</td>
<td>RCT</td>
<td>75 adult subjects (Ages 20-59) who met IHS diagnostic criteria for tension-type headache</td>
<td>Single chiropractic practitioner, Setting not explicitly described</td>
<td>SMT Group: HVLA, diversified or drop techniques, Deep friction massage</td>
<td>4 weeks, 8 visits</td>
</tr>
<tr>
<td>Tuchin (2000)</td>
<td>RCT</td>
<td>127 adult subjects (Ages 18-70) who met IHS diagnostic criteria for migraine headache</td>
<td>History of a minimum of 1 HA per month, University affiliated chiropractic research center</td>
<td>Experimental Group: SMT (HVLA – diversified technique), Control Group: Detuned interferential therapy</td>
<td>2 months, Up to 16 visits</td>
</tr>
<tr>
<td>Moraska (2008)</td>
<td>Cohort</td>
<td>18 subjects (Ages 18-45 years)</td>
<td>Tension-type headache, Setting not described</td>
<td>Massage therapy including myofascial release</td>
<td>6 weeks, 12 sessions</td>
</tr>
<tr>
<td>Borrman (2008)</td>
<td>RCT</td>
<td>42 subjects (Ages 18 to 65)</td>
<td>Mechanical neck pain &gt;6 wks, Hospital-based outpatient rehabilitation clinic</td>
<td>Group 1 (standard care): Hot pack, Ultrasound therapy, Exercise, Group 2: Standard care, Mechanical traction</td>
<td>2 weeks, 10 sessions</td>
</tr>
</tbody>
</table>

Legend:
- MCIC – Minimal Clinically Important Change
- RMDQ – Roland Morris Disability Questionnaire
- SMT – Spinal Manipulative Therapy
- HVLA – High Velocity Low Amplitude
- Mobs – Mobilization
- NRS – Numerical Rating Scale
- PM – Physical Modalities (hot packs, ultrasound, soft-tissue therapy, electrotherapy)
- NHP – Nottingham Health Profile
- VAS – Visual Analog Scale
- MVK – Modified Von Korff
- ODI – Oswestry Disability Index
- ADL – Activities of Daily Living
- LEFS – Lower Extremity Functional Scale
- 6MWT – Six Minute Walk Test
- TKA – Total Knee Arthroplasty
- GPE – Global Perceived Effect
- BQ – Bournemouth Questionnaire
- PGIC – Perceived Global Impression of Change
- GROC – Global Rating of Change
- WOMAC – Western Ontario and McMaster Universities Osteoarthritis Index
- PSFS – Patient Specific Functional Scale

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## Table 4: Treatment Response Based Upon Patient Classification Schemes

<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Initial F/U</th>
<th>Percent of Aggregate Improvement</th>
<th>Percent of Improvement for Unmatched Patients</th>
<th>Percent of Improvement After Patient Classification as Most Favorable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axen</td>
<td>Low Back Pain</td>
<td>2 weeks</td>
<td>66</td>
<td>36</td>
<td>91</td>
</tr>
<tr>
<td>Axen</td>
<td>Low Back Pain</td>
<td>2 weeks</td>
<td></td>
<td>30</td>
<td>84</td>
</tr>
<tr>
<td>Brennan</td>
<td>Low Back Pain</td>
<td>4 weeks</td>
<td></td>
<td>60</td>
<td>78</td>
</tr>
<tr>
<td>Hicks</td>
<td>Low Back Pain</td>
<td>8 weeks</td>
<td>34.6</td>
<td></td>
<td>74.8</td>
</tr>
<tr>
<td>Flynn</td>
<td>Low Back Pain</td>
<td>2-12 days</td>
<td>45</td>
<td></td>
<td>95</td>
</tr>
<tr>
<td>Fritz</td>
<td>Low Back Pain</td>
<td>1 week</td>
<td>45</td>
<td></td>
<td>85.5</td>
</tr>
<tr>
<td>Childs</td>
<td>Low Back Pain</td>
<td>1 week</td>
<td>45</td>
<td>7</td>
<td>92</td>
</tr>
<tr>
<td>Axen</td>
<td>Low Back Pain</td>
<td>2 weeks</td>
<td>21</td>
<td></td>
<td>79</td>
</tr>
<tr>
<td>Tseng</td>
<td>Neck pain</td>
<td>After 1 visit</td>
<td></td>
<td>60</td>
<td>89</td>
</tr>
<tr>
<td>Cleland</td>
<td>Neck Pain</td>
<td>&lt; 1 week</td>
<td></td>
<td>54</td>
<td>86</td>
</tr>
<tr>
<td>Cai</td>
<td>Radicular Low Back Pain</td>
<td>9 days</td>
<td></td>
<td>19.4</td>
<td>69</td>
</tr>
<tr>
<td>Currier</td>
<td>Knee Osteoarthritis</td>
<td>2 days</td>
<td>68</td>
<td></td>
<td>97</td>
</tr>
<tr>
<td>Iverson</td>
<td>Patellofemoral Syndrome</td>
<td>Immediate</td>
<td></td>
<td>45</td>
<td>80</td>
</tr>
<tr>
<td>Lesher</td>
<td>Patellofemoral Syndrome</td>
<td>Immediate</td>
<td></td>
<td>52</td>
<td>83</td>
</tr>
</tbody>
</table>

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Table 5: Recovery Patterns & Dose-Response Associated with SMT and/or Physical Therapy for Nonspinal Musculoskeletal Disorders

<table>
<thead>
<tr>
<th>Study</th>
<th>Disorder</th>
<th>Population &amp; Setting</th>
<th>Intervention</th>
<th>TX Period</th>
<th>TX Frequency</th>
<th>Outcome Variables</th>
<th>Follow-up Period</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kennedy (2008)</td>
<td>Post total knee arthroplasty</td>
<td>- 84 subjects - Mean age = 66 years - Initial in-patient physical therapy. Followed by...</td>
<td>Progressive rehabilitation program: - Range of motion - Strength &amp; endurance - Proprioception &amp; functional training</td>
<td>Inpatient = 1-2 weeks</td>
<td>Outpatient = discretionary</td>
<td>- 6MWT</td>
<td>- LEFS</td>
<td>- 17-days post-op</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Community-based physical therapy out-patient facilities - Home-based self care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Most improvement occurred within the first 12-weeks (post-op)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Little improvement occurred after 26 weeks</td>
</tr>
<tr>
<td>Deyle (2005)</td>
<td>Knee osteoarthritis</td>
<td>- 134 subjects - Mean age = 64 years - Out-patient physical therapy clinics at 3 military hospitals</td>
<td>Clinic Treatment Group: - Progressive rehabilitative therapy i.e., exercises and manual therapy</td>
<td>4 weeks</td>
<td>Clinic Group: - 8 sessions</td>
<td>Home Group: - 2 supervised sessions</td>
<td>- WOMAC</td>
<td>6MWT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Home Exercise Group: - Same exercises but no manual therapy</td>
<td></td>
<td>Home Group: - 2 visits</td>
<td>Supervised sessions</td>
<td>- Medication treatment only</td>
<td>- Both Groups: - 4 weeks - 8 weeks - 1 year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- No additional gains obtained after supervised care ended</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Improvement sustained at 1yr for both groups</td>
</tr>
<tr>
<td>Jubb (2008)</td>
<td>Knee osteoarthritis</td>
<td>- 88 subjects - Mean age = 64 years Hospital-based clinic</td>
<td>Acupuncture (manual and electro)</td>
<td>5 weeks</td>
<td>10 visits</td>
<td>- WOMAC</td>
<td>EuroQol</td>
<td>- End of treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Mild but not clinically significant loss of gains noted at 9 weeks</td>
</tr>
<tr>
<td>Coleman (2008)</td>
<td>Knee osteoarthritis</td>
<td>- 79 subjects - Adults &lt; 85 years - National healthcare system (Australia)</td>
<td>Group education: - Pain management strategies - Exercise advice - Balance/falls prevention - Behavioral support</td>
<td>6 weeks</td>
<td>6 sessions (2.5 hrs ea.)</td>
<td>- VAS (end of treatment only)</td>
<td>WOMAC</td>
<td>- End of intervention</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- 6 and 12 months</td>
</tr>
<tr>
<td>Van den Dolder (2006)</td>
<td>Patellofemoral pain syndrome</td>
<td>- 134 subjects - Mean age = 64 years - Out-patient physical therapy clinics at 3 military hospitals</td>
<td>Transverse frictional massage</td>
<td>2 weeks</td>
<td>6 sessions</td>
<td>- PFFSQ</td>
<td>Active knee F/E</td>
<td>Post intervention period (2 wks)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Significant improvements in active range of motion and physical performance were identified</td>
</tr>
<tr>
<td>DiFabio (1998)</td>
<td>Shoulder: - Adhesive capsulitis - Rotator cuff injury</td>
<td>- 4,850 subjects - ≥18 years old - 272 out-patient physical therapy clinics (geographically diverse)</td>
<td>Discretionary PM&amp;R services</td>
<td>20 days</td>
<td>10.2 visits (mean)</td>
<td>MOS-17</td>
<td>Reported as effect sizes</td>
<td>At end of treatment period</td>
</tr>
</tbody>
</table>

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**Pajareya (2004)**  
**Shoulder adhesive capsulitis**  
- 122 subjects  
- Mean age: 56 years old  
- 80% duration: >6 wks  
- Outpatient clinic  
- Diathermy  
- Mobilization  
- Passive and active exercises  
- 3 weeks  
- 3 visits per week  
- Global Rating  
- SPADI  
- ROM  
- Satisfaction  
- Medication use  
- 3 weeks  
- 6 weeks  
- 12 weeks  
- 24 weeks  
- 35% of study group subjects demonstrated a successful outcome at 3 weeks  
- 61.4% of study group subjects demonstrated a successful outcome at 6 weeks  
- No significant improvement at 12 and 24 weeks

**Senbursa (2007)**  
**Shoulder impingement**  
- 30 subjects  
- 30 to 55 years old  
- University out-patient clinic  
- Guided Self-Care:  
  - Active ROM, stretching and strengthening exercises  
- Physical Therapy Group:  
  - Manual therapy  
  - Exercise  
- 4 weeks  
- Self-Care Group:  
  - daily (10-15 minutes per day)  
- Therapy Group:  
  - 12 visits  
- End of treatment period  
- 3 months  
- Clinically meaningful improvement occurred for both groups at the end of the treatment period for the primary outcome (pain)  
- Physical measures showed measurable improvement  
- At 3-months half of the subjects reported ≥50% improvement

**Walther (2004)**  
**Shoulder impingement**  
- 60 subjects  
- 25 to 66 years old  
- Refractory to previous conventional PT and/or injections  
- Physical therapy clinics  
- Standardized Self-Training:  
  - Centering training  
  - Stretching  
- Physiotherapy Group:  
  - Centering training  
  - Stretching  
- Functional Brace Group:  
  - Coopercare Lapstrap  
- 12 weeks  
- Self-Care Group:  
  - 4 training sessions with PT  
  - 5x/wk (10-15 minutes per day)  
- Therapy Group:  
  - 30 visits  
- Brace Group:  
  - 12 hrs/day  
- VAS  
- Constant-Murley score  
- 6 weeks  
- 12 weeks  
- At 6 weeks:  
  - 40% of the patients reported significantly reduced pain level  
  - 30% of the patients were pain-free at rest  
  - 51% of the patients showed reduced pain at night  
  - 19% of the patients were pain-free at night  
  - 64% of the patients indicated pain during exercise was reduced  
  - There were no differences across intervention groups  
- At 12 weeks:  
  - All groups showed additional and similar improvement in both outcome variables

---

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<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Subjects</th>
<th>Ages</th>
<th>Setting</th>
<th>Intervention</th>
<th>Frequency</th>
<th>Test(s)</th>
<th>Follow-Up</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partridge (2000)</td>
<td>Post CVA</td>
<td>114 subjects</td>
<td>60-94 years</td>
<td>Hospital Stroke Unit</td>
<td>Bobath approach</td>
<td>60 minutes of therapy/day</td>
<td>Minimum of 6 weeks</td>
<td>Daily</td>
<td>POR, HAD, RLOC</td>
</tr>
<tr>
<td>Feys (1998)</td>
<td>Post CVA</td>
<td>100 subjects</td>
<td>36-88 years</td>
<td>Hospital Stroke Unit</td>
<td>Sensorimotor stimulation, Usual rehabilitation</td>
<td>60 minutes of therapy/day</td>
<td>Weekly</td>
<td>Daily (30 sessions)</td>
<td>Impairment: Brunstrom-Fugel-Meyer Test (MCIC = 10%) Discharge: Action Research Arm Test ADL: Barthel Index</td>
</tr>
<tr>
<td>Curnier (2007)</td>
<td>Knee osteoarthritis</td>
<td>60 subjects</td>
<td>51-79 years</td>
<td>Outpatient clinic</td>
<td>Hip mobilizations (Grade IV)</td>
<td>1 day</td>
<td>1 session</td>
<td>NRS, GRS (success)</td>
<td>48 hours after intervention</td>
</tr>
<tr>
<td>Iverson (2008)</td>
<td>Patellofemoral syndrome</td>
<td>50 subjects</td>
<td>21-65 years</td>
<td>Outpatient clinic</td>
<td>Lumbopelvic manipulation</td>
<td>1 day</td>
<td>1 session</td>
<td>NRS (50% improvement = success) GRS (moderate = success)</td>
<td>Immediately following intervention</td>
</tr>
<tr>
<td>Lesher (2006)</td>
<td>Patellofemoral syndrome</td>
<td>50 subjects</td>
<td>18-36 years</td>
<td>Outpatient clinic</td>
<td>Patellar-taping (medial glide technique)</td>
<td>1 day</td>
<td>1 session</td>
<td>NRS (50% improvement = success) GRS (moderate = success)</td>
<td>Immediately following intervention</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>van Rijn (2008) [97]</th>
<th>Acute lateral ankle sprain (Grades I-III)</th>
<th>Systematic Review</th>
<th>Various forms of conventional therapy:</th>
<th>Varied</th>
<th>Varied</th>
<th>Active ROM</th>
<th>Variable:</th>
<th>There was a rapid decrease in pain within 2 weeks</th>
<th>5-33% of patients experienced residual pain at 1 year follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>31 studies (24 high quality)</td>
<td>- Rest, ice, compression, elevation (RICE)</td>
<td>Varied</td>
<td>Varied</td>
<td>Pain scales</td>
<td>3-5 days</td>
<td>2, 4, 10 weeks</td>
<td>1 to 11 yrs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Immobilization</td>
<td>- Superficial heat</td>
<td>- Ultrasound</td>
<td>- ROM exercise</td>
<td>- Stretching exercise</td>
<td>- Strength exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Varied</td>
<td>- Varied</td>
<td>- Active ROM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Varied</td>
<td>- Group 1:</td>
<td>- Group 2:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Group 2:</td>
<td>- Standard supervised physical therapy</td>
<td>- Unassisted home-exercise program</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 6 weeks</td>
<td>- Group 1:</td>
<td>- Group 2:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 12 sessions</td>
<td>- ROM</td>
<td>- daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Grip strength</td>
<td>- PRWE (MCIC = 22.5 points)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Krischak (2009) [98]</td>
<td>Fracture of the distal radius after internal fixation with locking plates.</td>
<td>48 subjects</td>
<td>Ages 51-79 years</td>
<td>Hospital-based orthopedic surgery center</td>
<td>6 weeks</td>
<td>Group 1:</td>
<td>Grip strength</td>
<td>Both groups demonstrated meaningful improvement at 6 weeks</td>
<td>The home exercise group had ~50% greater improvement compared to the PT group</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 3-5 days</td>
<td>2, 4, 10 weeks</td>
<td>1 to 11 yrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:**

- 6MWT: 6-minute walk test
- WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index
- PFPSQ: Patellofemoral pain severity questionnaire
- PM&R: Physical medicine and rehabilitation
- MOS-17: Medical outcomes short form
- SPADI: Patellofemoral pain severity questionnaire
- VAS: Visual analogue scale
- ROM: Range of motion
- POR: Profiles of recovery scale
- HAD: Hospital anxiety and depression scale
- RLOC: Recovery locus of control scale
- GRS: Global rating scale
- MCIC: Minimal clinically important change
- HDI: Headache disability index
- PRWE: Patient related wrist evaluation
MTB – Decision Making Flow

1. **Subsequent Submission Received**
   - **Is Treatment for same condition?**
     - Yes: **MTB**
     - No: **Enter explanation in patient comment field, reset recovery milestones for a 1 month duration**

2. **Has there been a sufficient trial of care?**
   - Yes: **Is there a reason to anticipate a further MCIC?**
     - Yes: **MCIC** (Minimal clinically important change)
       - Overall relative change is at least 30%
       - FOA - 10% raw imp. on spinal indices;
       - 2 pt. NRS - for Chronic cases
       - 3 pt. NRS - for Acute cases
       - NRS score ≤ 4/10, a 1 point change = MCIC
       - NRS score of 5 or more; MCIC = 2 points
       - DASH = 15 points
       - LEFS = 9 points

   - No: **MTB (Maximum Therapeutic Benefit)**
     - 2/10 on NRS
     - 16% or less NDI or Oswestry Score
     - No plausible reason to expect further MCIC

3. **The patient is at MTB**
   - **Full denial:**
     - There is a record of previous contact regarding the topic of MTB with this provider
   - **MTB transition:**
     - May or may not have had a discussion
     - Room for some additional improvement however, not meeting MCIC
   - **Supportive Care**
   - **Contact provider:**
     - Render a supportable decision based upon dialogue:
       - Process of Care - appropriate?
       - Outcomes - improving?
       - Likely impact of continuing care?

Terms/Definitions:
- **Episode of Pain** – A period of pain lasting >24 hrs, preceded and followed by a period of at least one month without pain
- **Episode of Care** - Consultation or treatment preceded and followed by at least 3 months without treatment for the same complaint
- **Recurrent Pain** – Pain that is present on less than half the days in a 12 month period occurring in multiple episodes.
- **Chronic** – Pain reported on more than half the days in a 12 month period.
- **Flare-ups/Exacerbations** – Phases of increased pain/symptoms involving the same region, which may or may not be related to specific incidents, superimposed on a recurrent or chronic course. Most flare-ups/exacerbations return to MTB within 1 weeks; even severe occurrences usually reach MTB within 9 days
- **Persistent** - Pain occurring 30 or more days within the preceding 12 months.
- **Non-Persistent** - Pain occurring less than 30 days within the preceding 12 months.

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**Decision Guide for Informing Judgments in Making UR Determinations: Integration of the Global Rating Scale with Core Outcome Measurements**

### Scenario A

<table>
<thead>
<tr>
<th>Core Outcome Measures and Global Rating Scale AGREE</th>
<th>UR Decision Making</th>
<th>Clinical Considerations</th>
<th>Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>All outcomes favor the same direction i.e., improved or not improved</td>
<td>Straightforward: Improved or Not improved</td>
<td>Patient perception is aligned with valid and reliable outcome assessment tools (OA). Care management should be in accord with the likelihood of MCIC with ongoing care</td>
<td>High</td>
</tr>
</tbody>
</table>

### Scenario B

<table>
<thead>
<tr>
<th>Core Outcome Measures AGREE and Global Rating Scale DISAGREE</th>
<th>UR Decision Making</th>
<th>Clinical Considerations</th>
<th>Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core outcome measures are consistent for clinically meaningful improvement and GRS score is ≤5</td>
<td>Straightforward: Improved</td>
<td>Patient satisfaction with outcome is at variance with standard OA. Final status may be influenced by encouraging provider/patient discussion</td>
<td>High</td>
</tr>
</tbody>
</table>

### Scenario C

<table>
<thead>
<tr>
<th>Core Outcome Measures AGREE and Global Rating Scale DISAGREE</th>
<th>UR Decision Making</th>
<th>Clinical Considerations</th>
<th>Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core outcome measures are consistent for NO clinically meaningful improvement and GRS score is ≥6</td>
<td>Complex: Improved → Not improved</td>
<td>Lack of improvement as reported in standardized OA conflicts with the patient self-report, which typically is associated with a moderate-large treatment effect. Peer-to-peer outreach is indicated to ascertain the most likely ‘change-status’ of the patient. In the absence of peer-to-peer contact, consider a transitional determination.</td>
<td>Low to Moderate</td>
</tr>
</tbody>
</table>

### Scenario D

<table>
<thead>
<tr>
<th>Core Outcome Measures DISAGREE</th>
<th>UR Decision Making</th>
<th>Clinical Considerations</th>
<th>Confidence</th>
</tr>
</thead>
</table>
| Outcome measures for pain and disability are at variance. The GRS is in agreement with one of the standard outcome assessments | High Complexity: Improved → Not improved | The GRS can be helpful with informing judgment. Other factors to consider include:  
- the relative values placed upon types of outcomes i.e., pain reduction for acute vs. change in ADL for chronic  
- magnitude of clinical change in standard OA e.g., large change in pain level vs. modest change in pain  
- magnitude of change in GRS  
- probability of further MCIC | Moderate |
Utilization Management Policy

Policy History/Revision Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2006</td>
<td>Original effective date</td>
</tr>
<tr>
<td>12/04/2006</td>
<td>Annual review completed</td>
</tr>
<tr>
<td>4/10/2008</td>
<td>Annual review completed</td>
</tr>
<tr>
<td>1/15/2009</td>
<td>Policy placed into new format</td>
</tr>
<tr>
<td>4/30/2009</td>
<td>Annual review completed; MTB -Decision Guide added</td>
</tr>
<tr>
<td>7/16/2009</td>
<td>Policy revised and approved by QIC; Nonspinal disorders added to cited literature; Definitions updated; Decision Guide for interpreting standardized outcomes assessment tools in the context of global ratings was added; Plain Language Summary updated</td>
</tr>
<tr>
<td>4/08/2010</td>
<td>Annual review completed</td>
</tr>
<tr>
<td>10/26/2010</td>
<td>Policy rebranded to “OptumHealth Care Solutions, Inc. (OptumHealth)”</td>
</tr>
<tr>
<td>4/07/2011</td>
<td>Annual review completed</td>
</tr>
<tr>
<td>4/19/2012</td>
<td>Annual review completed</td>
</tr>
<tr>
<td>4/18/2013</td>
<td>Annual review completed</td>
</tr>
<tr>
<td>4/17/2014</td>
<td>Annual review completed; Policy rebranded “Optum* by OptumHealth Care Solutions, Inc.”</td>
</tr>
<tr>
<td>4/16/2015</td>
<td>Annual review completed</td>
</tr>
<tr>
<td>4/21/2016</td>
<td>Annual review completed</td>
</tr>
<tr>
<td>4/20/2017</td>
<td>Annual review completed; Legal entity name changed from “OptumHealth Care Solutions, Inc.” to “OptumHealth Care Solutions, LLC.”</td>
</tr>
</tbody>
</table>

Contact Information

Please forward any commentary or feedback on Optum utilization management policies to: policy.inquiry@optumhealth.com with the word “Policy” in the subject line.

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**Utilization Management Policy**

**PLAIN LANGUAGE SUMMARY**

**Maximum Therapeutic Benefit**

Utilization Management Policy # 84

*Plain Language Summaries are a service provided by Optum* by OptumHealth Care Solutions, LLC to help patients better understand the complicated and often mystifying language of modern healthcare.*

Plain Language Summaries are presented to supplement the associated clinical policy or guideline. These summaries are not a substitute for advice from your own healthcare provider.

**What is maximum therapeutic benefit and what is known about it so far?**

Musculoskeletal pain, especially spinal pain is a common problem. Traditional nonsurgical treatments that are helpful for some patients with musculoskeletal pain include physical therapy, manipulation (chiropractic), exercise and drugs (pain killers, anti-inflammatory drugs, and muscle relaxants). It is important to determine if a particular treatment is helping a person improve (*decreased pain and increase abilities to perform daily activities*). Most treatments reach a point where no further improvement can be expected. **This is called the point of maximum therapeutic benefit (MTB).** MTB can be reached when complaints either fully resolve, or when pain and/or disability persist – even with ongoing treatment.

It is not difficult or burdensome to measure improvement resulting from treatment. There are enough resources available for a healthcare provider to know when and how to measure improvement. With this information, the reasonable likelihood of additional improvement can be determined.

Most healthcare benefit certificates do not include treatment that is not resulting in a reasonable expectation of further improvement from that particular treatment.

**How was Maximum Therapeutic Benefit evaluated?**

A work group of clinicians was assigned to review the available research. The internet was searched for policies and articles that provided information about 1) when during the course of care is it reasonable to measure for improvement; 2) methods to measure improvement in pain and/or disability; 3) the probability of further improvement with a continuation of treatment; and 4) the likelihood that stopping treatment will result in a worsening of either pain or disability.

After gathering and analyzing this information, a policy was presented to a series of committees that included independent health care practitioners.

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What did the work group find?

- Most individuals can expect to notice measurable improvement in pain and/or disability early during the course of care – within 2 to 6 weeks after beginning treatment.
- If improvement has not occurred with 6 weeks of treatment, it is highly unlikely that continuing treatment will be helpful.
- When initial improvement did occur, many studies showed no additional lasting improvement beyond 6 to 12 weeks of treatment.
- Most flare-ups resolve quickly – within a few days to 3 weeks.

What were the limitations of the information?

While there is increasing amount of information about nonspinal conditions e.g., shoulder, knee, ankle, etc., the majority of research is related to spinal conditions (low back and neck pain, sciatica, etc.). The timelines for improvement may not be applicable to some types of post-surgical care.

What are the conclusions?

An individual has reached MTB when after at least 2 to 6 weeks of treatment one of the following is present:

- complaints have resolved or stabilized
- there has been improvement; however, there is no reason to expect further improvement with the same care
- there has not been improvement in pain and/or disability (based on standardized assessments)
- there is insufficient information in the healthcare record to determine that improvement has occurred.

What are the options once MTB has been reached?

Once MTB has been reached it is the responsibility of the healthcare provider to:

a) Revise the plan of care based upon current research evidence
b) Discharge a patient from active/therapeutic care
c) Recommend an alternate type of treatment by a different healthcare provider

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